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Certificate of Need

Washington State Department of Health
October 6, 2005



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Certificate of Need (CON)

- Roles and Functioning of CON
 - Overview
 - Background and History
 - Activities Subject to Review
 - Review Criteria
 - Program Challenges
- Acute Care Licensing and CON Relationships
- Review of Non Hospital Based Surgery
- Questions

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Overview

Certificate of Need approves needed new health care projects, permitting orderly development without de-stabilizing the existing system.

- Approve projects that are likely to succeed financially.
- Avoid causing a major impact to rates.
- Not approve applicants with a record of providing poor quality care.
- Not approve projects with a better alternative.



Background and History

The Decade of the 70's

- State and regional health planning is authorized.
- Certificate of Need is required for hospital and nursing home construction and acquisition projects over \$100,000.
- CON is updated to comply with the federal National Health Planning and Resources Development Act.
- The act specified a governance process and broadened the scope of CON.
- Dollar threshold requiring CON approval increased to \$150,000.

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Background and History The Decade of the 80's

- CON is updated several times for clarity and to address general issues.
- Expenditure thresholds for review are raised several times.
- Applicants denied a CON are allowed adjudicative appeal.
- The federal Health Planning Act is repealed.
- The Hospital Commission is sunsetted.
- Most capital expenditures exempted; only Nursing Homes still have a requirement.
- Law changed to reflect the establishment of the Department of Health.

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Background and History The Last 15 Years

- Several changes to address rural facilities.
- Addition and updating of nursing home bed banking law.
- Several adjustments to nursing home need calculation.
- Standing for adjudicative appeal were modified to include affected parties.
- Review of methodologies applied to tertiary heart care directed.
- Hospice care centers added to CON.

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Reviewable Activities

Establishment of new health care facilities

- Hospitals
- Nursing Homes
- Kidney Dialysis Centers (ESRDs – End Stage Renal Dialysis Centers)
- Medicare Home Health Agencies
- Medicare Hospice Agencies
- Ambulatory Surgical Centers
- Hospice Care Centers

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Reviewable Activities (continued)

Capacity Increases for:

- ESRDs
- Hospitals
- Nursing Homes
- Hospice Care Center

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Reviewable Activities (continued)

New Tertiary Service

- Level I Rehabilitation Programs
- Open Heart Surgery
- Organ Transplantation
- Specialty Burn Services
- Intermediate Care Nursery
- Level II Obstetric Services
- Neonatal Intensive Care Units
- Specialized Inpatient Pediatric Services
- Level III Obstetric Services

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Reviewable Activities *(continued)*

- Sale, purchase, or lease of hospitals
- Nursing Homes Capital expenditures over \$1M (adjusted for inflation--currently \$1.2M)
- Nursing home bed banking transactions
- Replacement of existing Nursing Homes

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General Review Criteria

- Need
- Financial Feasibility
- Structure and Process of Care
- Cost Containment

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The Need Criterion

- There is a public need for the project
- Existing services/facilities will not be sufficient
- Access is improved to all residents of the service area

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The Financial Feasibility Criterion

- Project costs are properly addressed
- Project costs not likely to cause an unreasonable growth in service costs
- Cost factors of the project are within normal limits

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The Structure and Process of Care Criterion

- Qualified staff are available or can be recruited
- Necessary relationships to ancillary and support services
- The service can/will comply with all applicable statutes and rules
- The service will have a positive relationship with, and not fragment the existing health care system
- Assurances exist that services provided will be safe and appropriate

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The Cost Containment Criterion

- There are no less costly, more efficient or more effective approaches
- The project involves improvements or innovations which promote cost containment, quality of care and cost effectiveness

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Program Challenges

Clarity regarding

- “Tie Breakers” – who should be awarded when all applicants are qualified but not all are needed?
- Criteria for financial feasibility – what is to be considered?
- What is a tertiary service?
- What constitutes “unnecessary duplication”?
- What to considered a “better alternative.”

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Program Challenges

- Role of the Department after award
 - Is the role of CON only as a “gateway”?
 - Is there, or should there be, explicit authority to enforce standards and conditions post award?
- No review of effectiveness of decisions
- Length and complexity of appeal processes
- Data availability to support evidence basis of decisions

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Certificate of Need and Licensing in Acute Care Services

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General Hospital Licensing

- RCW 70.41 – facility that provides 24 hour or more continuous care, observation, diagnosis for two or more people suffering from illness, injury deformity, abnormality or other condition for which obstetrical, medical or surgical services would be appropriate.
- RCW 70.41.090 – after June 30, 1989, no hospital shall initiate a tertiary health service unless it has received a certificate of need.

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Psych Hospital Licensing

- RCW 71.12 – facility receiving or caring for any mentally ill, mentally incompetent or chemically dependent person whether owned/operated by private entity or county or municipality, or public hospital district.

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Hospital Licensing & CON

- Must have a Certificate of Need before obtaining license as a new health care facility.
- License bed capacity established by Certificate of Need.
- Must have a Certificate of Need before providing a tertiary care service.
- No explicit statutory authority in 70.41 or 71.12 to enforce certificate of need decisions or conditions of award.

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Home Health & Hospice Agency

- Administer or provide two or more home health services to ill, disabled, infirm or vulnerable individuals in temporary or permanent residence. Services include nursing, home health aide, physical therapy, occupational therapy, speech therapy, respiratory therapy, nutritional services, medical social services, home medical supplies/equipment services.
- Administer or provide hospice services to terminally ill individuals in temporary or permanent residence. Services include symptom and pain management, emotional, spiritual and bereavement support and home health services.

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Home Health/Hospice Licensing & CON

- May license a home health or hospice agency without first obtaining a Certificate of Need
- Must have a Certificate of Need before obtaining Medicare Certification
- No explicit statutory authority in 70.127 to enforce certificate of need decisions or conditions of award

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Hospice Care Center

- A homelike non-institutional facility where hospice services are provided and meet requirements for operation which include ownership/operation by a licensed hospice agency, have 20 or fewer beds, & constitute no more than 49% of the patient care days of a hospice agency.

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Hospice Care Center Licensing & CON

- Must have a Certificate of Need before obtaining license to include bed capacity
- No explicit statutory authority in 70.127 to enforce certificate of need decisions or conditions of award

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Federal Medicare Programs

- Home Health Agency – must have CON
- Hospice Agency – must have CON
- Ambulatory Surgery Center – must have CON determination
- Renal Dialysis Facility – must have CON

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Future Considerations: Non-Hospital Based Surgery

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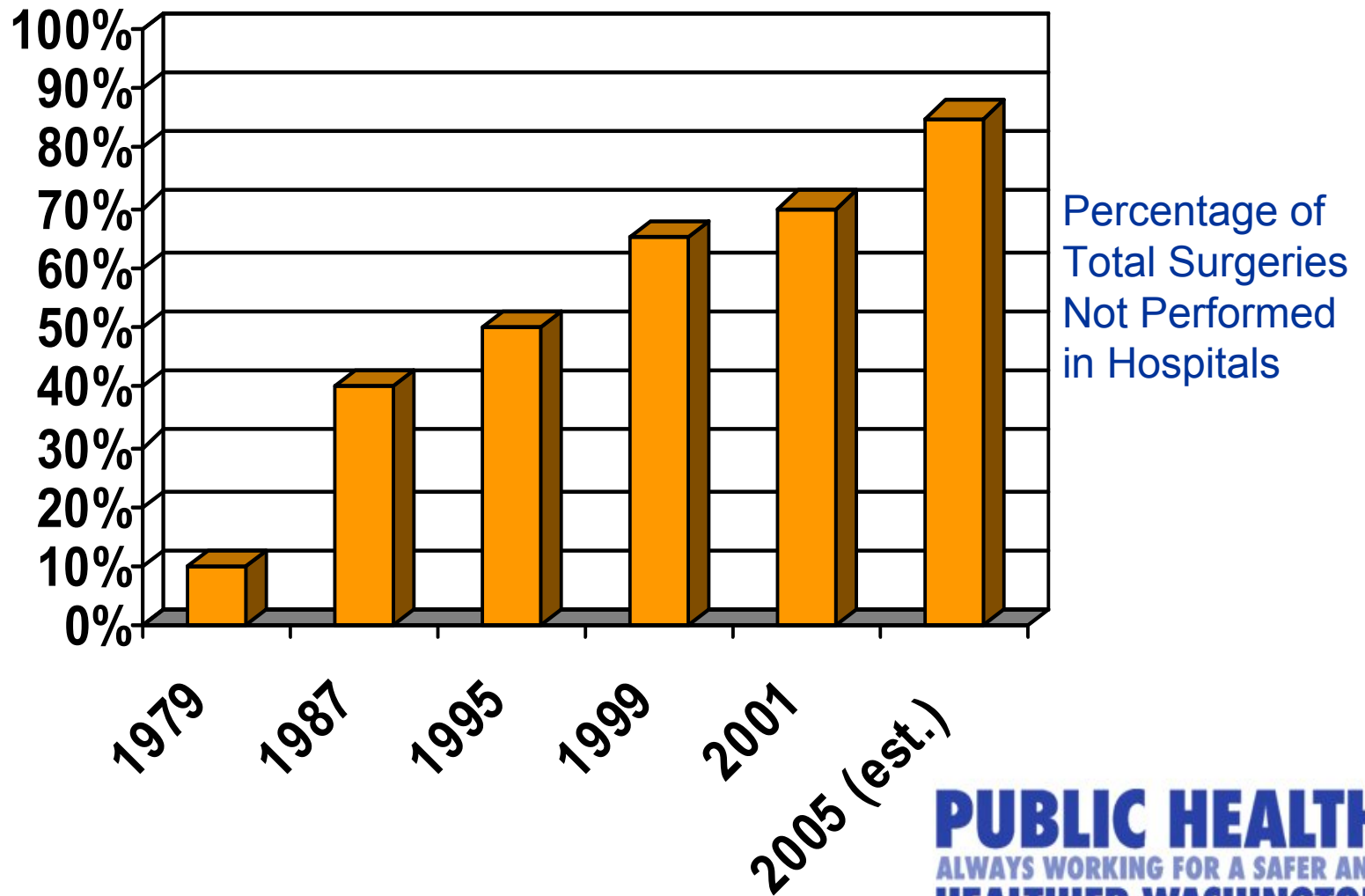
Non-Hospital Based Surgery

- Also often called “office-based surgery”
- Surgery conducted in offices, clinics, ambulatory surgery centers, other non-hospital sites
- Factors often included:
 - Level of anesthesia
 - Condition of patient
 - Type of procedure
 - Invasiveness
 - Duration of procedure and recovery

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- Changes in industry and economics in the last two decades have shifted a significant number of surgeries into non-hospital settings
- Regulation of practitioners does not address adequacy of setting
- Regulation of hospitals does not address alternate settings
- A gap in regulation

Non Hospital Surgery A Growing Trend



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Policy Considerations

- Should state law define what constitutes non-hospital based surgery?
- Should Washington State have requirements regarding oversight and setting of standards?
- Should requirements be practice or facility based?
- Should there be requirements for reporting adverse events?
- Are requirements for national accreditation or other certification of non hospital surgery appropriate?

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Next Steps

- DOH review information from public work sessions
- Analyze policy issues
- Regulate or Not?
- Recommendation

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Questions?

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